Volume XVI, Number 7 Monday, May 18, 2009

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Inaccurate Lab Results: What Happened in Canada?

MANY OF YOU HAVE HEARD ABOUT THE WIDELY-PUBLICIZED PROBLEMS with laboratory testing in several locations across Canada in the past few years. We update the situation with a fascinating intelligence briefing on pages 9-12.

The first lab scandal to catch the public's attention was the discovery that, between 1997 and 2005, an anatomic pathology laboratory in St. John's, Newfoundland, had gone seriously off course with its estrogen receptor (ER) and progresterone receptor (PR) testing program. Subsequent reviews determined that at least 396 breast cancer patients got inaccurate results. Just last month, four years after these problems were identified, the parent health system announced it had "discovered" another 43 breast cancer patients who should have had their lab tests reviewed, but were missed by the review team. So even at the provincial health level, there were failures to accurately audit and identify all breast cancer patients tested during the 1997-2005 period.

However, what fascinates me is the second chapter in this story. In the wake of the public disclosures about ER/PR testing failures in Newfoundland and Labrador, several other provincial health systems in Canada did reviews of pathologists practicing within their region. In three hospitals in three provinces, these reviews uncovered serious failures in anatomic pathology test accuracy and reliability. As you will read, in at least two cases, it was the hospital's head of pathology who was determined to have done deficient work, reaching back at least two or more years! One pathologist had an error rate of about 5% in the initial review of past cases. Another's error rate was 6%.

Critics are quick to point out that, in Canada, laboratory accreditation, certification, and proficiency testing is a matter left to the provinces. One consequence of this arrangement is that Canada lacks national laboratory quality standards. However, I have a more fundamental question: has reduced funding for anatomic pathology services contributed to these serious breaches in laboratory test integrity across multiple hospitals and laboratories?

Could it be that salaries are inadequate to attract and retain competent pathologists in some Canadian provinces? Has the health system cut back on pathology training slots in medical schools as a way to save money in the short term—while negatively affecting patient care in the long term? My hunch is that 30 years of serious cost reductions to lab testing services across Canada may have finally reached the point where inadequate financial resources devoted to lab testing contributes to further breakdowns in the quality of patient care. TDR

Despite the Recession, Many Local Labs Thrive

Secret is priority emphasis on lab operations, complimented with strong outreach sales effort

CEO SUMMARY: Each year, the Executive War College offers useful perspectives on the current lab testing marketplace. This year's gathering took place as the recession deepened. Yet that didn't dampen the optimism and energy of 60 speakers and more than 450 attendees from 12 countries. Collectively, the 60 sessions offered credible evidence that those labs emphasizing operational excellence in tandem with a professional outreach sales effort are holding their own, despite the tough economy.

IN THE MIDST OF THE DEEPEST ECONOMIC RECESSION experienced by this country since 1981-82, a goodly number of local labs and hospital laboratory outreach programs are posting admirable gains in specimen volume, revenue, and net profit.

Moreover, the lab administrators and pathologists leading these successful lab organizations are quite optimistic that their laboratories will continue to outperform both the economy and their laboratory competitors. This development has two particularly interesting elements.

First, why are many local and regional clinical laboratories doing so well at a time of economic contraction? Second, could the ability of these same laboratory organizations—coming at a time when employees are becoming more frugal with their spending on healthcare services and companies are pruning back staffing levels—be a sign that the balance of competitive advantage could be swinging back to local laboratories and away from their big national lab competitors?

At the 15th Annual *Executive War College on Laboratory and Pathology Management*, conducted on April 28-29, 2009, in New Orleans, more than 60 expert speakers presented their management strategies and shared their successes. Common elements to the winning accomplishments of these lab organizations provide at least partial answers to the two questions listed above.

As to why so many local labs are prospering during tough economic times, one important reason is that they run their laboratory with management discipline and operational excellence. This plays out

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes *THE DARK REPORT* plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but we cannot guarantee the accuracy of all information.

visit: www.darkreport.com • © The Dark Group, Inc. 2009 • All Rights Reserved

in two ways. One, these laboratory organizations are good at reading their local market and developing a strategic plan that exploits the most lucrative opportunities and generates cash flow that is used to: a) internally finance ongoing expansion; and b) return cash profits to the parent hospital or health system.

Lab Operated As A Tight Ship

Two, these labs are equally disciplined at operating a tight ship. That means use of Lean/Six Sigma quality management methods to continously improve the quality of testing services while squeezing out unnecessary costs. It means diligence in coding/billing/collections with the goal of presenting 100% clean claims at first submission. At these labs, sales and marketing programs are professional and productive. The resulting volume of new specimens is profitable and provides the cash flow to fund further growth.

Examples of all these strategic and operational themes were evident at the *Executive War College*. For example, the current recession is hitting the state of Michigan and the city of Detroit with full strength. Yet, the laboratory division at **Henry Ford Health** is expanding its outreach market share while raising service levels in ways that appeal to physicians and patients.

Henry Ford Health's Success

These strategies, market outcomes, and operational achievements were shared in different sessions by Richard Zarbo, M.D., Senior Vice-President and Chair, Pathology and Laboratory Medicine; and John Waugh, Director of Laboratory Operations. Zarbo described how the use of the Henry Ford Production System is transforming quality and work flow within surgical pathology. For his part, Waugh explained how tight clinical and operational integration of laboratory services within seven hospitals and 40 ambulatory care centers at Henry Ford has been leveraged to generate significant operational cost savings while supporting aggressive growth in outreach specimens and revenue.

Tackling the question of whether the competitive market pendulum may be swinging back in favor of local and regional laboratories, the Henry Ford Health Laboratory case study at the *Executive War College* provides evidence of this trend.

More anecdotal evidence in favor of the this assessment was provided by Marc Grodman, M.D., CEO of **Bio-Reference Laboratories, Inc.** (BRLI) of Elmwood Park, New Jersey. In his strategic case study, Grodman turned back the clock to May 2000, when he first addressed the *Executive War College*. At that time, BRLI was a $59 million lab company and Grodman laid out his strategy to expand market share in the greater New York City market while building specialized testing businesses. At this year's *Executive War College*, Grodman explained how BRLI is now a $350 million lab company, with a significantly larger share of the New York City market.

Broad Attendee Consensus

These examples are only a small sampling of the broad and comprehensive range of laboratory management sessions. With more than 450 senior lab administrators and pathologists in attendance from 12 countries, the audience's validation of remarks made by the speakers adds credibility to the insights presented here.

All of this is not to say that the clinical laboratory industry is immune to the consequences of a shrinking economy and the larger number of unemployed in this country. These are tough times and they challenge laboratory managers at all levels.

On the other hand, lab administrators and pathologists should not ignore the fact that there are a large number of clinical labs and pathology groups which remain profitable and are even able to grow. These are the labs which can teach us how to guide our own labs to financial sustainability and clinical excellence, even during a recession. TDR

CMS Refuses to Return Competitive Bid Docs

Labs and trade groups are concerned that CMS will use the proprietary information in other ways

CEO SUMMARY: The Acting Secretary of Health and Human Services (HHS) has refused the request of three San Diego-area labs for the return of their bid documents—even though the competitive bidding demonstration project was repealed by Congress last July. The HHS Acting Secretary says he has no obligation to return the documents and he intends to use the information in the bid applications for "analysis purposes," according to court papers filed last month.

WHY WOULD THE FEDERAL **Centers for Medicare & Medicaid Services** (CMS) retain the bid documents from the San Diego competitive demonstration bidding project more than a year later?

An unknown number of laboratories submitted bid documents in February 2008 to participate in the Medicare Clinical Laboratory Services Competitive Bidding Demonstration project that CMS intended to implement later that year in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area). But CMS was blocked from implementation on two fronts.

First was the court victory on April 8, 2008, when three plaintiff labs were granted a preliminary injunction by a U.S. District Court Judge in San Diego. This injunction prevented CMS from proceeding with the laboratory competitive bidding demonstration. *(See TDR, April 14, 2008.)* Then, just months later, in July 2008, Congress voted to rescind the law that authorized the demonstration project.

Following the favorable federal court decision in April 2008, the three plaintiff laboratories next requested the court to direct CMS to return the bidding documents, destroy all copies in their possession, and agree not to use the information in the bidding documents for other purposes.

To date, the Secretary of Health and Human Services (HSS) has refused to return the bid documents, saying in court filings that he was under no obligation to do so—and perhaps more worrisome for lab directors, he stated that he intends to use the information in the bid applications for "analysis purposes."

Return Of Documents

That is why the three plaintiff laboratories returned to federal court on April 27 to state their belief that allowing CMS to keep the documents and use the bidding information in those documents would cause them irreparable harm. In a complaint for injunctive relief, the plaintiff labs argued that CMS should return the documents and never use the information from the bidding documents.

In the strongly-worded complaint, the plaintiff labs asked the U.S. District Court for the Southern District of California to prevent acting HHS Secretary Charles

Johnson and HHS staff from ever using any of the information from any bid application submitted under the laboratory testing demonstration project.

The plaintiffs further asked the court to order CMS to return all bid applications the bidders submitted, to destroy any paper or electronic copies of the bid applications, and to declare that the secretary has no legal authority to retain the bid applications submitted under the demonstration project or to use any information in the bid applications. The labs also seek to have CMS pay for the costs of the suit and reasonable attorneys' fees.

Intransigent In Dealings

The plaintiffs are **Sharp HealthCare**, **Internist Laboratory**, **Scripps Health**, along with the **American Association of Bioanalysts (AAB)**, and the **American Clinical Laboratory Association (ACLA)**. The plaintiffs charge that Secretary Johnson has been intransigent in his dealings with the plaintiffs, saying in court papers, "… due to the secretary's intransigence and disregard for the strictures of federal law, the flawed demonstration project still is causing harm to clinical laboratories, including the plaintiffs herein or their members." The complaint was filed by the plaintiffs' attorneys, Patric Hooper, Jordan Keville, and Abigail Wong of **Hooper, Lundy & Bookman, Inc.**, in Los Angeles.

At one point during negotiations between the plaintiff labs and the secretary of HHS over the past year—and before the demonstration project statute was repealed—the plaintiffs said they would voluntarily dismiss the case if the secretary would stipulate not to use the information contained in the bid applications submitted in connection with the demonstration project for any purpose, including setting Medicare reimbursement rates for laboratory services.

The HHS secretary refused. Instead, his only offer was to not disclose proprietary information that identifies individual bidders.

Court records show: "Those applications contained extensive information about the laboratories submitting them, including information of a confidential and proprietary nature and even personal information about the laboratories' owners and directors. The secretary represented at all times prior to when the bid applications were submitted that the information contained therein would be used for the purposes of declaring winners under the demonstration project and setting the demonstration project payment rates. However, with the demonstration project statute now repealed, the secretary nevertheless refuses to return the bid applications to the laboratories that submitted them and, even more troubling, has represented that he intends to use the information set forth in those applications for some yet undisclosed purpose."

The three plaintiff labs are raising important issues on behalf of the entire laboratory industry. After Congress rescinded the law, the Medicare Clinical Laboratory Services Competitive Bidding Demonstration was ended. So what is the motive of CMS in refusing to return bidding documents?

Important Issues For Labs

After all, from the very start, the serious flaws and problems with the competitive bidding demo's design and implementation were obvious to any informed observer. Thus, for CMS to indicate that it would like to retain access and use of these documents and information for other purposes raises the spectre that confidential financial information provided by certain labs for one bureaucratic fiasco will be put to use in inappropriate—even illegal ways—to the detriment of clinical laboratories and the long term disadvantage of Medicare beneficiaries.

Thus, intervention by a federal court may be the only way these plaintiff laboratories and lab associations might stop CMS from using these bid documents for other purposes. TDR

Pathology Innovations

Using Cellphones Like Microscopes To Help Lesser-Developed Countries

Researchers create "microscopes without lenses" that can transmit pathology images using cell phones

LAB PROFESSIONALS WHO HAVE worked in regions like Africa know that the infrastructure in developing countries is limited or nonexistent. This makes it challenging to provide clinical laboratory testing services that are up to the standards common in developed countries.

For example, it can be difficult for a laboratory in a developing country to report lab test results in a timely fashion to those clinicians practicing medicine in remote settings that lack the fixed telephone and Internet services taken for granted in developed countries. That is why there is keen interest in finding ways to use cellular phones to support better clinical care in developing countries.

For example, researchers at the **University of California, Los Angeles** (UCLA), and the **University of California**, Berkley (UC), are developing ways to use cellphones to collect and transmit bio-medical data specifically to help laboratory professionals and physicians make diagnostic and treatment decisions. Researchers at each university are collecting images in different ways. In April, research teams at both UCLA and UC won awards from the **Vodafone Americas Foundation**, a foundation funded by the international cellphone company to promote innovative wireless technology.

At UCLA, the innovative technology is called LUCAS, which stands for Lensfree Ultra-wide field Cell-monitoring Array. It is based on Shadow imaging. Unlike most medical imaging technology, LUCAS involves viewing a hologram, or shadow image, of cells and cell structures. It is called the "CelloPhone Project" by the team of Drs. Aydogan Ozcan, Neven Karlovac, and Yvonne Bryson, and other colleagues in UCLA's electrical engineering department.

"There are parts of the world unfortunately that don't have medical resources," stated UCLA's Ozcan. "There are no [clinical] laboratories. There is no infrastructure; so there is no way to get [lab test] results. There is nothing out there to provide basic tests regarding patients' health. Labs are too expensive.

"Cellphones Are Everywhere"

"But cellphones are everywhere, even in Africa!" continued Ozcan. "Almost 20% of the population uses cellphones actively and we can capture [medical] images with just a cellphone and wirelessly transmit that image to a personal computer workstation. The results of the analysis can be sent back via text message."

Ozcan's development is particularly remarkable because it involves collecting, transmitting, and analyzing holograms of cells to detect disease using the image sensor of a digital camera. Essentially, it allows microscopic particles to be viewed without using lenses.

To achieve this, Ozcan removed the cover of the sensor of a digital camera and placed cell samples directly on the imaging sensor. The pixels on the image sensor captured a shadow image of the cells. "That was the remarkable moment when I said, 'Yes,' This is going to work," Ozcan

explained. He then noted that the holographic image of the cells contains more information about the shape and the health of the cell than a regular microscope can detect.

"We can detect holograms of cell bacteria digitally," he said. "For each cell we want to analyze, we have library images of the same hologram of the same cell type. We load the library images of that hologram and the algorithm does pattern matches so we can identify the cells based on what we have in our library of images. If there was a disease like malaria, for instance, you would see the hologram of those red blood cells showing the deficiencies so that disease would actually show a contrast difference."

For imaging and monitoring of discrete particles such as cells or bacteria, Ozcan believes viewing the shadow images is a better way of viewing cells and cell structures than is possible with current technology. "Technically, the shadow of a micro-object can be thought of as a hologram that is based on interference of diffracted beams interacting with each cell," he explained. "Micro-scale shadows (or transmission holograms) contain an extremely rich source of quantified information regarding the spatial features of the micro-object of interest."

Installing the requisite imaging technology adds about $50 to the cost of a cellphone and the system is about 90% accurate, Ozcan said. More information about Oxcan's research can be found at *http://innovate.ee.ucla.edu.*

Overcoming Challenges

At UC Berkley, researchers are using cellphones to collect and transmit microscopic images for analysis. The "CellScope Project," as it is called, is based on a mobile microscopy system. A compact optical microscope is attached to a cellphone with a digital camera. The device is designed to reduce the need for expensive microscopes in the field.

Drs. Daniel Fletcher, Erik Douglas, and Wilbur Lam, along with other researchers in the Bioengineering Department at UC Berkeley, hope their mobile microscopy system will increase the capabilities of healthcare workers in resource-limited areas. They observe that optical microscopy is the diagnostic gold standard for many diseases, but the necessary equipment and trained personnel often are unavailable in a resource-poor area. However, a number of resource-limited areas in developing countries have reliable cellular communication systems. Thus, cellphones can be one affordable and reliable method to help clinicians diagnose patients in remote areas.

CellScope's Potential

UC Berkeley's CellScope is capable of on-site disease diagnosis and wireless transmission of patient data to clinical centers for further evaluation, treatment recommendations, patient management, and epidemiological studies. Details can be found at *http://fletchlab.berkeley.edu/research_cellscope.htm.*

THE DARK REPORT observes that the ubiquitous nature of the cellphone gives it the potential to become an inexpensive and useful laboratory tool in lesser-developed countries and regions. That is one reason why researchers at UC and UCLA are developing ways to capture and move bio-medical data by cellphone.

However, there is wider significance to these research initiatives that will be of interest to pathologists and pathology practices administrators. The two examples provided above illustrate how new cellular and wireless technologies have the potential to be disruptive to pathologists and the laboratory medicine profession.

In fact, as first movers in the pathology profession begin to utilize digitized pathology images, the ability of cellular telephones and wireless technology to move these images cheaply and with high resolution may actually increase the disruptive effect these two technologies have on anatomic pathology. TDR

ER/PR Testing in Canada Continues to Make News

Cameron Report cites deficiencies, yet Canada seems slow to implement tighter lab accreditation

CEO SUMMARY: In Canada, the story about inaccurate breast cancer testing just won't go away. In March, the Cameron Report was made public with its assessment of lab testing failures in Newfoundland and Labrador. In April, the health system in those provinces admitted that it needed to review and possibly retest another 43 breast cancer patients. Calls for a uniform system of laboratory proficiency testing and accreditation have not yet motivate federal and provincial health officials to tackle this issue.

SERIOUS DEFICIENCIES IN BREAST CANCER TESTING continue to make national headlines in Canada. Three times in the past 90 days, media stories about laboratory problems have captured the attention of the public.

The first event to dominate the news cycle was release of the Cameron Report on March 3. This was a major review of failures in estrogen receptor (ER) and progesterone receptor (PR) tests performed in Newfoundland and Labrador from 1997 to 2005. It is believed that laboratory failures may have caused at least 396 patients to get inaccurate results during this time.

Inaccurate Cancer Tests

Exactly one month later, on April 3, another disclosure made national headlines. That was the day that officials of **Eastern Health** in Newfoundland and Labrador publicly admitted that the breast cancer tests of another 43 patients will undergo review. Potential problems with laboratory testing for these patients had apparently gone undetected, despite the health service's earlier efforts to identify all breast cancer patients whose laboratory test results may have been inaccurate.

In the wake of these two developments, *The Toronto Globe and Mail* newspaper then published its assessment of events. Collectively, these issues have kept laboratory testing failures in the public eye across Canada. For lab managers and pathologists in the United States, these developments may speak to how funding cutbacks for laboratory test services over many years can quietly erode the quality and integrity of laboratory testing.

Taking each event in order, it was March 3 when the Cameron Report was released to the public. This is the most recent product of the Commission of Inquiry on Hormone Receptor Testing, which was organized in 2007 to investigate the problems with breast cancer testing in Newfoundland and Labrador between 1997 and 2005.

Author of the Cameron Report is Margaret Cameron, a judge in the Supreme Court of Newfoundland and Labrador, Court of Appeals. As authorized by the Commission on Inquiry, she heard testimony from 93 witnesses over 138

days. Judge Cameron's findings were published in a 495-page report that focused on the problems with estrogen receptor (ER) and progresterone receptor (PR) tests performed in Newfoundland and Labrador from 1997 to 2005.

A Series of Problems Cited

The Cameron Report is a compilation of the testimony given by patients or relatives of patients during the hearings. Their stories illustrate the many different ways that problems with ER/PR testing affected patients.

In her report, Cameron explained that she was prohibited from expressing any conclusions or making recommendations regarding civil or criminal responsibility of any person or organization. Consequently, Cameron noted that she made no attempt to identify the specific reasons for the problems with breast cancer testing for the individual patients.

Following this disclaimer, Cameron's report outlined a long list of problems that caused at least 386 breast cancer patients to get inaccurate test results. She described how, as a result of the inaccuracies, physicians used faulty laboratory test results to determine treatment.

Of the 386 breast cancer patients originally identified by Eastern Health as having received potentially inaccurate PR/ER test results, at least 108 have since died. Health officials concede that it is unlikely anyone will ever know how many patients died, if any, as a result of not getting appropriate breast cancer care.

Test Problems Discovered

Problems with breast cancer testing in Newfoundland and Labrador were first detected in 2005. That's when doctors questioned the hormone receptor test results of a patient with invasive lobular carcinoma, a form of breast cancer.

"The [PR/ER] testing inaccuracies were the result of a failure of accountability and oversight at all levels of Newfoundland and Labrador's healthcare system, Cameron wrote. "The whole of the health system, to varying degrees, can be said to have failed the ER/PR patients. There was a failure of both accountability and oversight at all levels."

During her investigation, Cameron heard testimony about one laboratory in St. John's that processed the botched tests. In testimony before Cameron, witnesses identified problems that included: 1) staff shortages in the laboratory; 2) lack of proper internal controls; and, 3) improperly trained staff in the laboratory. Witnesses also reported infighting among medical staff, communication lapses between the Newfoundland government and Eastern Health, and failed attempts at damage control.

The second event followed just one month later. On April 3, Eastern Health announced that test results from another 38 breast cancer patients were going to be reviewed to determine if they were accurate. A few days later, Eastern Health raised to 43 the number of patients whose laboratory tests would be reviewed. It also disclosed that 27 of these patients have died, although what role inaccurate lab tests may have played in these deaths is unknown.

Days after scathing criticism by Danny Wilson, Premier of Newfoundland and Labrador about how these patients have been handled, Pat Pilgrim, Chief Operating Officer for Cancer Care at Eastern Health conducted a press conference, where she said "To our patients, we realize how distressful this is to them—to be hearing from us now, almost four years later, that we missed you; you should've been on a list for retesting; and now we have identified you and we will be retesting you. We apologize to our patients for that. We wish that we could undo that, but we cannot undo it and we do have to give them the information that we have."

While these problems were in the news, *The Toronto Globe and Mail*

reported that little progress has been made to adopt national standards for clinical laboratories. For most clinical labs in Canada, proficiency testing (PT) is voluntary. But in British Columbia and Ontario, it is mandatory and the success of a program in British Columbia to standardize testing, called the Diagnostic Accreditation Program, was spurring calls for health regulators in all of the Canadian provinces to adopt mandatory PT. *(See TDR, September 8, 2008.)*

The *Globe and Mail* also reported on April 1 that dozens of breast cancer lab tests in British Columbia, done between May of 2005 and October of 2006, were being reviewed after Kirk Ready, M.D., a pathologist and former clinical director of the **Okanagan Health Service Area Laboratories**, in Penticton, British Columbia, wrote a letter to the provincial health authorities voicing concerns about how the lack of uniformity and other issues in breast cancer testing at the Okanagan laboratory may have resulted in misinterpretation. In the weeks since Dr. Ready's letter was made public, health officials determined that there were no misdiagnoses of breast cancer patients whose specimens were handled by this laboratory.

Problems In Other Provinces

In its coverage of Canada's problems with breast cancer testing, The *Globe and Mail* revisited the list of laboratory test problems that became public news in recent years. Once problems with pathology testing became public in Newfoundland and Labrador, other provinces uncovered inaccuracies in pathology testing. Inaccurate pathology diagnoses took place in these provinces:

•**February 2008, Miramichi, New Brunswick:** Pathologist Rajgopal Menon, M.D., left his position as head of pathology at **Miramichi Regional Hospital** following a review of 227 cases of prostate and breast cancer biopsies from 2004-2005. These independent reviews determined that: 1) 18% of the cases had incomplete results; 2) 3% were misdiagnosed; 4) 41 cases included incomplete protocols or examinations and or miscalculated the stage of the cancer; and, 5) compared to the original diagnosis, there were seven cases of undetected cancer, and four additional cases that were possibly cancerous. Health officials announced they would review as many as 24,000 cases. Menon characterized this review as "unjustified and unfair." He filed a civil suit against the regional health authority.

Commission of Inquiry Issues ER/PR Report

It was 2007 when the Commission of Inquiry on Hormone Receptor Testing was established by the Government of Newfoundland and Labrador. Judge Margaret A. Cameron was appointed commissioner and asked to inquire into, and report on, problems with estrogen receptor (ER) and progesterone receptor (PR) tests conducted between 1997 and 2005 in the Newfoundland and Labrador health care system.

The inquiry was further tasked with determining the cause of problems in the laboratory, when these problems were discovered, and what laboratory protocols were in place during the time in question. Judge Cameron was also asked, as part of the inquiry, to examine whether the estrogen and progesterone hormone receptor testing systems and quality assurance processes currently in place are reflective of "best practices" in laboratory medicine.

As a point of interest, the commission was instructed not to express any conclusions or recommendations regarding the civil or criminal responsibility of any person or organization. Judge Cameron concluded the public hearings in October 2008. The Cameron Report is available as a three-part report in PDF format on-line at *http://www.cihrt.nl.ca/default.htm*.

•**May, 2008, Winnipeg, Manitoba:** Pathologist Robert Stark, M.D., was put on leave from his position as head of the pathology department at **St. Boniface Hospital**. The outside pathology review of this lab, including approximately 822 of the cases diagnosed from February 2008 and complex cancer cases dating back to March 2007, determined that errors were made in at least 42 cases and two patients received the wrong cancer diagnosis due to error.

•**May, 2008, Owen Sound, Ontario:** After routine quality control testing identified an error by pathologist Barry Sawka, M.D., at **Owen Sound Hospital**, a more detailed review of 600 of his cases was launched. **Grey Bruce Health Services**, the local health authority, determined that the error rate was 6%, which health officials stated was six times the "the normal error rate for pathologists." These misdiagnoses lead to errors in treating patients.

Government Support Needed

One recommendation in the Cameron Report was that, "to prevent a public health disaster," a government-backed national program for accreditation and quality testing at hospital labs should be established.

The *Globe and Mail* pointed out that, before such improvements in pathology testing could be made to local and provincial health systems in Canada, pathologists would need the authority and financial support of federal authorities and of each provincial government. The newspaper quoted Newfoundland Health Minister Ross Wiseman stating that federal intervention is required. Federal authorities said the government will not become involved because the regulation of pathologists and laboratories is a provincial and territorial responsibility.

For laboratory administrators in the United States, the problems with anatomic pathology testing surfaced to date in Canada are instructive. Back in the second half of the 1980s, Canada was one of the first developed nations in the world to begin consolidating laboratory testing services regionally. In several provinces, health officials were active and aggressive in eliminating excess laboratory capacity and driving down reimbursement paid for laboratory testing services.

Thus, could these instances of systemic breakdown in the accuracy, integrity, and reproducibility of anatomic pathology testing be the first symptoms of a pathology infrastructure that is ready to unravel at the seams in certain regions of Canada?

High Stress in Newfoundland

Take Newfoundland and Labrador as an example. In the wake of this lab testing scandal, experts noted that specimen volume increased in Eastern Health by 20% from 1999 to 2005. Yet low pay meant that the pathologist turnover rate during the years 2003-2007 was 32%.

Moreover, despite an additional stipend granted pathologists in Newfoundland and Labrador to encourage retention and recruitment, Eastern Health has failed to maintain adequate staffing of pathologists. Joseph Tumilty, M.D., President of the **Newfoundland and Labrador Medical Association**, stated in April 2008, that these two provinces were short by 12 to 15 pathologists. In fact, the laboratory at St. John's, where the ER/PR testing problems happened, should be staffed at about 18 pathologists. Yet, at one point in 2008, it was down by six positions.

It is provincial health authorities which establish the budgets and physician reimbursement levels. Pathology staffing and quality problems in Newfoundland and Labrador may be the canary in the coal mine—reminding us that when funding for laboratory testing services falls to an inadequate level, it is patients who feel the brunt of the cost savings, in the form of inaccurate lab test results that lead to the wrong care. TDR

Biotech Start-Up Firms Hiring Lab Professionals

Early-stage molecular companies are recruiting experienced lab administrators, pathologists, MTs

CEO SUMMARY: It may be a tough job market right now for laboratory professionals. But investors, lured by the potential of personalized medicine and molecular diagnostics, continue to pour investment capital into new companies. In turn, these companies are actively recruiting experienced clinical lab managers, pathologists, and technical staff. One management recruiter specializing in biotech placements offers insights and advice on how clinical lab professionals can tap these job opportunities.

In response to the declining economy, many laboratories in hospitals and health systems are reluctant to fill open management positions. Some labs are even pruning back both administrative and staff positions.

That means laboratory professionals may have a more difficult time finding a job in this down economy, compared to recent years. But Valerie August sees a bright spot for experienced lab administrators and professionals. "Biotech continues to need talent and regularly taps clinical laboratory managers, pathologists, Ph.D.s, and medical technologists (MTs) to fill open positions," stated August, who is President of **Valerie August & Associates, LLC**, a biotech recruitment firm based in New York City that conducts national and international searches.

"Personalized medicine is a hot sector and investors continue to fund new firms," observed August. "Even in the current economic doldrums, we see a growing number of biotech startups focused on molecular diagnostics, imaging technology, and point-of-care (POC) testing. As a result, this steady stream of newly-formed biotech companies creates job opportunities for experienced laboratory professionals.

August does have a caveat about these jobs. "Start-ups are small companies with few established routines and the need to prepare new technology for the marketplace. To succeed in these working environments, managers and laboratory professionals must be ready to wear many hats, assume multiple roles or responsibilities, and be adaptable to rapid changes in the daily work routine," she explained.

Match Skills To Employer

"Any clinical laboratory professional considering employment with a biotech company should also be careful that their particular skills are a good match for such a prospective employer," continued August. "I regularly see good opportunities for pathologists. That's because many new molecular technologies are intended to provide diagnostic knowledge from tissue.

"Demand is also strong for lab managers and administrators who possess marketing and sales skills," she added. "Medical technologists and supervisors looking for a change might consider a

field-based position in technical support or sales."

The jump from established routines in a clinical laboratory to a field-based position in an early-stage biotech company often proves to be too big of a leap in company culture for some people. "I work mostly with early-stage biotech firms that have zero room for error when putting together their management and technical teams," she said. "As a result, it is essential to identify candidates who are comfortable with multiple responsibilities and capable of working in a swift-changing environment."

Personalized Medicine Firms

August further said that biotech companies organized around personalized medicine products and services have generated a high demand for laboratory professionals with a background in genetic counseling and genetic testing. "It is the same for pathologists, Ph.D.s, technical staff, and lab managers with experience and skills in molecular diagnostics," stated August. "At the moment, many in this field are optimistic that the Obama administration and the federal Department of Health and Human Services (HHS) will provide increased funding and favorable policy decisions to accelerate the adoption of personalized medicine in this country.

Proposed Legislation

"For example, Congress is currently considering a federal budget amendment that promotes use of personalized medicine in comparative research," explained August. "The law is intended to drive evidence-based medicine and it will also prohibit insurers from denying treatments and services based on an insured's DNA results. Another bill in Congress would set up a mechanism to coordinate genetic medicine policies between agencies, along with a way for individuals to have control over how their personal genetics information is used."

One point of interest for laboratory professionals working in clinical labs is the difference in compensation offered by biotech companies. "Early-stage biotech firms generally pay higher salaries than clinical laboratories and working in these settings can be very rewarding," observed August.

"How much more these companies pay depends on three basic factors: experience, type of job, and level of position," she explained. "For support positions, the starting point in pay is about $60,000 per year. For mid-level management positions, compensation usually is in the range of $100,000 to $120,000. For senior positions, the starting point is about $200,000 and can go up from there, depending on the candidate's capabilities and the needs of the hiring biotech company.

"By contrast, in clinical laboratory settings, typical salaries for experienced medical technologists with relevant skills can be $51,000 to $61,000. Similarly, lab manager salaries are bracketed between $70,000 and $95,000, while directors in clinical labs may be paid between $92,000 and $116,000," stated August. "Don't forget that early-stage companies usually give stock option incentives, as well.

Cost Of Living Issues

"Another element that is incorporated into the compensation package is location, added August. "Companies located in San Francisco, New York, or Boston generally pay higher salaries than companies located in regions with a lower cost of living."

August's comments about the sustained interest by investors in molecular diagnostics and genetic medicine draws attention to one reason why the biotech sector continues to attract investment dollars. In turn, these new companies must actively recruit qualified laboratory executives, pathologists, and technologists to achieve their business goals.

This is a positive development for laboratory professionals, particularly individuals interested in using their skills in a commercial business setting as compared to a clinical laboratory setting. It also illus-

Making the Jump from Clinical Lab to Biotech: Matching Skills, Temperament, and Talent

CLINICAL LABORATORIES ARE ORGANIZATIONS with well-established routines and clear lines of management authority. By contrast, biotech start-ups can be free-wheeling environments, where change—not routine—is the order of the day.

As a management recruiter, Valerie August, President of Valerie August & Associates, LLC, of New York City, must carefully match a candidate's skills, personality, and temperament to the needs of a start-up company's working culture and business goals. To determine if a candidate's personality matches a startup firm's operating culture, August will ask the candidate about past jobs that he/she liked or disliked the most.

"Take the example of the candidate who tells you they don't like to be micromanaged," she stated. "Moments later, the candidate then tells you that he/she disliked a job because 'the operations director was not around much, there was no one to help me, or I was on my own too much.' I tell a candidate like this that, if they like structure, they won't like working for an early-stage company.

"By contrast, early-stage biotech companies often have external field-based positions," continued August. "These jobs can be rewarding for self-motivated, proactive people who can work solo. Typically, these are work-from-home positions and provide some flexibility. In addition, perks can include a company car, a laptop, and a Blackberry or other communication gadget."

"There is a downside to work-from-home positions," she added. "Some people discover they feel isolated when working from home. They miss the support an organization provides. Also, because there is no secretary or administrative help, at-home workers must type their own memos and reports."

For technical professionals, like medical technologists, August is careful to explain important differences from a daily working routine in a clinical laboratory and the dynamic activities required for technical support and sales in an early stage biotech company. "First, I recommend that clinical professionals start in a field-based technical support position before they consider moving into a sales job," she said.

"Technical support can be very rewarding because it allows an individual to use his/her training, while providing customers much needed assistance," August stated. "If the territory is large, travel can be significant. Also, customers complain, so these individuals need the skills to be tactful and deal with unhappy customers. People who have been at the bench in a clinical laboratory often don't have the stomach for dealing regularly with irate customers.

"Also, when these individuals start out in technical support," she said, "it gives them an opportunity to observe the stress of meeting sales quotas and responsibilities endured by the sales staff. Many decide to remain in a technical support role."

trates why commercial employers continue to compete for—and draw off—experienced laboratory professionals from clinical laboratories. As well, it is a reminder that some sectors of labor market continue to be dynamic, even if the economy is in the doldrums. **TDR**

—P. Kirk

Contact Valerie August at 212-678-9245 or email at: vaugust@augustbiotech.com.

New Report: POC Market Will Grow 30% by 2013

New technology and smaller instruments offer advantages to patients, providers, health systems

CEO SUMMARY: It will be no surprise to lab directors and pathologists that Kalorama Information, in its latest report on point-of-care (POC) testing, estimates that glucose testing comprises 67% of this market segment. What is notable is Kalorama's prediction that worldwide POC testing will grow by 30% during the next four years. Because of new portable and handheld instruments, POC testing is migrating from hospitals to workplaces, homes, disaster sites, and convenience clinics.

Is point-of-care (POC) testing poised to draw off specimens that currently flow into high-volume core laboratories? While the answer to this question is "not likely anytime soon," POC testing nevertheless is projected to grow by 30% in the next four years!

This estimate comes from a new report by **Kalorama Information**, a publisher and market researcher in New York City that specializes in reporting on biotechnology, diagnostics, healthcare, medical devices, and pharmaceuticals. Kalorama defines point-of-care testing as diagnostic testing at or near the site of patient care.

Last year, the worldwide market for POC *in vitro* diagnostic (IVD) tests totaled an estimated $13.3 billion. According to Kalorama, this means POC is about 28% of the overall $44 billion *in vitro* diagnostic testing market. Self-testing POC accounts for $8.525 billion, and professional POC testing accounts for $4.78 billion.

Kalorama estimates that, in the next four years, the market for POC *in vitro* diagnostic testing will grow by over 30%, reaching a total of $17.8 billion by 2013. "At that point it is anticipated that point-of-care testing will represent a bit larger share of the total IVD market, nearly 31%," said the report, *Point of Care Diagnostics,* April 2009.

Glucose, Critical Care Tests

It will be no surprise to lab directors and pathologists that glucose testing represents 67% of all POC testing, making it the undisputed leader in the field. Critical care testing represents the second-largest POC segment at 8%, and pregnancy testing is third at 5%.

Other POC testing segments and their share of total volume are: Infectious diseases–3%; cardiac markers–3%; fecal occult blood–3%; cholesterol/lipids–2%; HbA1c–2%; hemoglobin–2%; and other coagulation–2%.

Kalorama believes that several factors are driving the growth in POC testing. Notably, it considers managed care in the United States as a main growth driver, stating that "managed care's obsession with cost reductions is pushing the need for testing nearer the patient, as well as decentralized testing in the home, at the

bedside, and in the physician's office." THE DARK REPORT observes that Kalorama is predicting that managed care recognizes that a point-of-care test—even if more expensive than the same assay done in a high volume core laboratory—can often improve patient outcomes while reducing the total cost of that patient encounter. If this proves true during the next few years, clinical labs will need a strategy that allows them to participate in POC testing done in patient settings.

Innovation From Technology

Second, technology is driving innovation in the field of POC testing. Kalorama points out how increasingly smaller and more sophisticated transportable, portable, and handheld instruments have played a significant role in helping this form of diagnostic testing migrate from hospitals out to other settings, such as workplaces, homes, disaster sites, and most recently, convenience clinics in retail outlets. The third factor encouraging more POC testing is the increase in wellness testing.

Another interesting development is the use of different specimen types. Kalorama reported that "manufacturers are increasingly introducing minimally invasive [POC] tests that can be easily performed on a patient's saliva, urine, breath, or other bodily by-products.

Demographics Fuels Demand

"The new technologies and distribution channels enabling this shift have occurred in response to ongoing demographic changes that are creating a larger market for the [POC] products," the report said. "As the U.S. population continues to age, while at the same time living longer, it is becoming increasingly susceptible to a range of medical conditions that require identification."

Kalorama further noted that increased utilization of point-of-care testing is the result of healthcare professionals—in their search for faster, easier, and cheaper ways of diagnosing illness. POC diagnostics are finding ready acceptance as the most appropriate approach in decision-sensitive situations, including emergency departments and operating rooms.

The report listed the spectrum of diseases where POC testing now plays a role.

Infectious Disease Testing Is Fueling POC Demand

LAST MONTH'S OUTBREAK of A/H1N1 influenza demonstrated once again why there is a need for *in vitro* diagnostic IVD) technology than can test great numbers of patients quickly and accurately for infectious disease.

In its report titled "Point of Care Diagnostics," Kalorama Information estimated that the world market for rapid infectious disease tests was estimated at $424 million in 2007. The infectious disease tests performed most often are for influenza, hepatitis, HIV, Strep A, and respiratory viruses (such as influenza).

Kalorama predicts that miniaturized molecular assays will be increasingly competitive with rapid immunoassays. The need for higher levels of sensitivity and specificity are likely to encourage faster adoption of miniaturized molecular assays that offer clinicians more accuracy, reliability, and reproducibility than competing rapid immunoassays.

Even though at least 75 vendors worldwide market POC test kits for infectious disease, these tests have not been used widely in physicians' offices for two reasons, the report said. First, many of these tests do not fit the current physician office routine. Second, many of these tests are not as sensitive as lab-based tests. Recognizing that these tests lack the sensitivity of lab-based tests, physicians still need confirmation with a lab-based assay. "Therefore it is more efficient to send samples to a central lab," the report concluded.

These include: patients with diabetes; cancer; strep throat, influenza, and pneumonia; sexually transmitted diseases; and high cholesterol and other cardiovascular disorders.

Infectious Disease Testing

In the field of infectious disease, rapid tests are available for a wide range of conditions, such as: HIV, gonorrhea, syphilis, chlamydia, herpes, hepatitis, strep A, strep B, tuberculosis, RSV, influenza, legionella, mononucleosis, mycoplasma pneumonia, E. coli, H. pylori, cryptosporidium, giardia, C. difficile, rotavirus, fungal disease, and bacterial meningitis.

Another interesting insight for lab managers and pathologists is Kalorama's conclusion that physician office laboratories (POLs) are eager users of point-of-care tests for screening, diagnosis, and patient monitoring. It says that POL demand is a major source of increased utilization of POC testing. Also, as POC tests become more reliable and easier to perform, that encourages office-based physicians to expand the menu of POC tests they regularly use within their practice—and that in turn further increases demand for these tests.

Home Monitoring Growth

For laboratory professionals interested in home-based POC testing, Kalorama has big expectations for this segment. It predicts that glucose monitoring will continue to be the largest sector of POC testing. In particular, the growing incidence of chronic diseases, particularly diabetes, means that the volumes of these tests will increase strongly in the coming years.

Kalorama doesn't overlook the trend of walk-in rapid clinics in retail outlets. Pharmacy chains and such retailers as Wal-Mart have built thousands of these "rapid clinics" over the past five years. "If present trends continue, and assuming that the retail clinic model remains viable and is not hampered by regulation or professional resistance, retail clinics could see, conservatively, three times the sales of POC diagnostics as this segment is producing today," declared the report.

Kalorama observes that one problem with offering laboratory tests in these retail-based medical clinics is that the majority of individuals seen in such clinics do not return to receive the results of their lab tests. That means if the test results are positive, the patient is likely to remain untreated.

Point-of-care testing provides a solution to that situation. It means the clinic can give the patient an answer during that same visit, and treatment can be started immediately. This is why Kalorama believes that retail walk-in clinics will be an important source of demand for new POC tests in the coming years.

Home Monitoring Growth

With its prediction that point-of-care will experience 30% growth during the next four years, Kalorama is bullish on the prospects for POC testing. However, that statistic hides the fact that the lion's share of this testing is glucose self-testing by patients.

Thus, the market segment of point-of-care tests that could divert specimens currently going to clinical laboratories represents a smaller fraction of the overall lab testing pie. It is likely that these types of point-of-care tests won't be a disruptive threat to clinical labs during the next four years that Kalorama covers in its report.

However, most lab managers and pathologists recognize that POC tests will continually improve because of new innovative technologies. Increased accuracy and reliability, combined with smaller, faster test kits and analyzers, will encourage providers to make greater use of these POC tests in their medical practices. Over time, this means point-of-care testing will be competing for specimens with centralized clinical laboratories. TDR

Contact Kalorama at 800-298-5603 or www.kaloramainformation.com

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Experts are watching hospital finances to see whether slumping economic activity and growing unemployment rates are having an impact. At for-profit **Tenet Healthcare Corporation**, same-hospital paying admissions declined by 1.3% from Q1-08 to Q1-09. Tenet also said that its bad debt ratio of 6.8% had only increased by 0.1% from the same quarter last year. At **Hospital Corporation of America** (HCA), same facility admissions declined 0.9% in Q1-09 compared to Q1-08. HCA does not report its bad debt ratio in the same manner as Tenet. It did say that "same facility uninsured admissions declined 0.1% in the first quarter of 2009 compared to the prior year's first quarter.

ADD TO: Uninsured

It is noteworthy that both for-profit hospital companies reported only modest changes in the volume of inpatient admissions and equally modest changes in bad debt or uninsured admissions. It is a sign that, in the geographical regions where each company operates hospitals, increased unemployment rates in the community have yet to trigger a significant increase in uninsured admissions and/or increased bad debt related to uninsured care. This is auspicious, given that the current recession is now more than one-year old. Clinical lab managers and pathologists will want to keep an eye on uninsured patient ratios and associated bad debt to stay ahead of any developing problems.

MORE PEOPLE USE CELL PHONES THAN LAND LINES

As part of the National Health Interview Survey regularly conducted by the **Centers for Disease Control and Prevention** (CDC), researchers have determined that, for the first time, the number of households opting *only* for cell phone service now exceeds the number of households which have only landlines. The CDC survey determined that 20% of U.S. households rely exclusively on cellphones, compared to 17% of households which have only landlines and no cellphones. CDC researchers observe that this is an important shift in American society. It demonstrates how cellphones are supplanting land lines as the primary source of telephone service to growing numbers of Americans. In order for laboratories to communicate with patients who no longer have land lines, it will be necessary to collect the patient's cellphone number at the time when specimens are collected.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how **CNN** recognized "Heroes in Lab Coats" with a feature blog on its Web site. It stated that: "The wider world seldom gives them a thought until suddenly we realize we need them."

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 8, 2009.

Now in its third year!

Lab Quality Confab

on Quality Management in Diagnostic Medicine

September 29-30, 2009
Hilton Hotel • Atlanta, Georgia

It's the best source of operational excellence, cost-saving opportunities, and proven paths to improved quality!
Lean—Six Sigma—ISO 15189 • Powerful Case Studies!
Master Classes on Quality Methods • Hands-on Learning
Lessons from Innovative Labs • Access Experts, Vendors, Products
Exhibition Hall & New Products

Want to present? Send us your topic!
email: rmichel@darkreport.com, today.

Look for new topics and speakers soon!
visit www.labqualityconfab.com

UPCOMING...

- ***Lessons for All Labs from the A/H1N1 Outbreak: Why Clinical Labs in U.S. "Dodged the Flu Bullet."***
- ***How Cloud Computing and SAAS May Soon Give Laboratories More Informatics at Less Cost.***
- ***Multi-Modality and Multi-Analyte Diagnostics Ready to Make Inroads in Pathology and Radiology.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE New Service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends